JS 2/23/22
RJA 2/24/22

[redacted]

P-18-0307

Chemical Name: [redacted]

CASRN: [redacted]

ASSIGNMENTS	NAME	DATE
SAT Chair	Rebecca Daiss	09-21-2018
HH Hazard Assessor (A)	Sailesh Surapureddi	09-21-2018
HH Hazard QC Reviewer (A)		Date Reviewed
HH Risk Assessor FOCUS (B)	Chris Brinkerhoff	FOCUS Date: 10/15/2018
HH Risk QC Reviewer (B)	Sailesh Surapureddi	10-13-2018

Human Health Report Status:		DATE COMPLETED
X	HAZARD DRAFT- Pending Review	09-26-2018
	HAZARD REVIEWED	
	HAZARD FINAL	
X	RISK DRAFT- pending review	10/12/2018
X	RISK REVIEWED	10-13-2018
X	RISK-FOCUS FINAL- Uploaded	10-15-2018
	POST-FOCUS UPDATE DRAFT	
x	POST-FOCUS UPDATE FINAL- Uploaded	03/21/19

[redacted]

1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, available PMN data, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard, and other structural information
Based on the hazard determination and available quantitative risk information, EPA concludes that there is risk for the PMN substance.

1.1 Hazard Summary

1.1.1 Absorption / Metabolism

Absorption is nil all routes based on physical/chemical properties. Absorption of LMW ([redacted] <500 [redacted] <1000) is uncertain as LMW components are not identified.

1.1.2 Structural Alerts

N/A

1.1.3 Hazard Concerns

Systemic and lung effects for potential low molecular weight components (e.g., [redacted].

1.2 Exposure and Risk Characterization

1.2.1 Workers

Risks were identified for workers for systemic toxicity via dermal contact based on quantitative hazard data for a low molecular weight component of the new chemical (MOE = 20; benchmark MOE = 100).

Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including dermal protection (e.g., impervious gloves).

Risks were not identified for workers for lung toxicity via inhalation based on quantitative hazard data for a low molecular weight component of the new chemical (MOE = 213; benchmark MOE = 100).

1.2.2 General Population

Risks were not identified for the general population for systemic effects via drinking water exposure based on quantitative hazard data for a low molecular weight component of the new chemical (MOE_{adult}= 6,739; MOE_{infant}=1,604; benchmark MOE = 100).

1.2.3 Consumers

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.

[redacted]

1.3 Potentially Useful Information:

1.3.1 Assumptions and Uncertainties

Absorption of the PMN is based on p-chem properties
There are no measured data on the PMN substance itself
Health effects are based on LMW components which are unidentified
Potential low molecular weight components (e.g., [redacted]
Air releases are below threshold, therefore general population inhalation were not quantified

1.3.2 Potentially Useful Information

Toxicokinetics
Specific target organ toxicity

[redacted]

2 HUMAN HEALTH HAZARD- PART A

2.1 Chemistry Summary

PMN: P-18-0307	Submitter: [redacted]			Manu.	Import
Max. PV (KG): [redacted]		Binding Option Marked:			X
MW: [redacted]	[redacted]	% < 500	[redacted]	% <1000	CASN[redacted]

PMN Structure	Prop.	Meas.	Est.
[redacted]	MP	81	
	BP		>400
	Pres.		at 760 mm Hg
	VP		<0.000001
	S-H2O		[redacted]
	log P		

Analogues: [redacted]

USE: [redacted]

2.1 SAT Summary

2.1.1 Absorption

Absorption is nil all routes based on physical/chemical properties. Absorption of LMW [redacted] <500 [redacted] <1000) is uncertain as LMW components are not identified.

2.1.2 SAT Health Summary

There may be health concerns for potential low molecular weight components (e.g., [redacted] The polymer could be made differently with a higher percentage of LMW fractions. Acute toxicity and mutagenicity data were provided with a Sustainable Futures submission.

2.1.3 Exposure Routes of Interest

Route of Interest	
X	Inhalation:
X	Dermal:
X	Ingestion:

[redacted]

2.2 Toxicity Data

2.2.1 PMN Data (study summary, POD, same-as)

Data Submitted with the PMN

Acute oral Toxicity Rat – LD50 > 1000 mg/kg.

Ames Assay Salmonella & E Coli – negative with and w/o metabolic activation

2.2.2 Analogue/Metabolite Data (chemical, structure, study summary, POD)

Analogues: [redacted]

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(38) ANALOGUES:

PMN or CAS No.	Chem. Name	Structure	TSCA Y/N
[redacted]			N
			Y
			N
			Y

Acute Tox: LD50= >2000mg/kg

Eye irritation: Uncertain- conjunctival irritation cleared in 7 days

Dermal irritation: Negative

[redacted]

2.2.3 **SDS Data** (composition, hazard identification, toxicological information)

Speci

*For tl

Dispo
P501

[redacted]

[redacted]

[redacted]

*The s

**For

[redacted]

No

Ge

[redacted]

[redacted]

[redacted]

Dev
Exp

[redacted]

Hun
Skir
No s

2.2.4 Other Information

[redacted]

- NOEC of 24 ppm based on 13 week inhalation study in F344 rats. Respiratory and nasal lesions at 76 ppm and an oral/dermal NOAEL = 15 mg/kg-day (converted from the inhalation study).
- Repeated dose studies of the [redacted] (structure below) in rats and dogs suggest liver and developmental concerns with a LOAEL of 25 ppm for the liver effects and a NOEL of 100 mg/kg-day for developmental effects.

2.3 Human Health Category (From US EPA 2010 document)

Chemical Category: Not applicable
Chemical Category Health Concerns: Not applicable
Category Testing Strategy: Not applicable

2.4 Point of Departure Selected and Basis

2.4.1 POD for [redacted] may present in the LMW fraction-Uncertain for Inhalation

POD type: NOAEC
POD Value: 87mg/m^3
POD Chemical: [redacted]
POD Route: Inhalation
POD Hazard Endpoint: lung toxicity, nasal and ocular irritation
POD Basis: based on effects seen at 76 ppm (HEC = 32.63 mg/m3 and 1.55E+4 ug/m3

[redacted]

POD Benchmark MOE: 100 (10x intraspecies and 10X interspecies)
Reference: ECHA database for [redacted]
Note: this POD is only relevant for inhalation because effects are in the respiratory tract and can reasonably be assumed to be route specific therefore should not be extrapolated to other routes.

2.4.2 POD for [redacted] may present in the LMW fraction-Uncertain for Oral

POD type: NOAEL
POD Value: 20 mg/kg-day
POD Chemical: [redacted]
POD Route: Oral
POD Hazard Endpoint: tremors and/or shaking of the head in the 40 mg/kg dose group. This occurred intermittently at first and eventually occurred continuously in a few animals
POD Basis: based on effects seen in the 40 mg/kg-day dose group
POD Benchmark MOE: 100 (10x intraspecies and 10X interspecies)
Reference: ECHA database for [redacted] (repeated dose toxicity oral study #2)

3 HUMAN HEALTH RISK (PART B)

3.1 USES and EXPOSURES

3.1.1 Uses

[redacted]
This is a Sustainable Futures case.
[redacted]

3.1.2 Worker Exposure

3.1.2.1 Inhalation

MFG: negligible
USE: [redacted]
PDR: 3.0E+1 mg/day over [redacted] days/yr [redacted]: [redacted] OSHA PNOR PEL Limiting Model. Cm = 3 mg/m3, h = 8 hr/day.

3.1.2.2 Dermal

MFG: PDR 1.6E+3 mg/day over [redacted] days/yr [redacted]

USE: [redacted] PDR 4.5E+2 mg/day over 250 days/yr [redacted]

[redacted]

3.1.3 General Population Exposure:

3.1.3.1 Drinking Water

ADR as high as 4.24e-2 mg/kg/day and LADD as high as 5.95e-5 mg/kg/day

3.1.3.2 Fish

Based on fate assessment, the PMN was not evaluated as persistent and bioaccumulative

3.1.3.3 Air/Inhalation

Predicted environmental fugitive air and stack incineration release(s) were not assessed for the acute and chronic scenarios, as they are below modeling thresholds.

3.1.4 Consumer Exposure

No identified consumer exposures

[redacted]

3.2 RISK CALCULATIONS

3.2.1 Worker Calculations

Inhalation: Lung toxicity based on LMW component

Worker Margin of Exposure (MOE) Calculations using Animal Inhalation POD and Engineering Report PDR

	Animal or Human POD			Worker Exposure				Human Breathing Rates						Benchmark MOE	Endpoint Type
Exposure Route	POD Conc. mg/m^3	POD Period hrs/day	POD Duration days/wk	Exposure mg/day Potential Dose Rate (PDR)	Total Worker Breathing Volume for PDR Exposure Period m^3	Worker Exposure Duration Hours/Day	Exposure Duration Days/Wk	Default	Worker	Structural Alert as % of PMN	POD Conc - Duration & Breathing Rate Correction $Scenario_{HEC}$ mg/m^3	Exposure TWA mg/m^3	**Margin of Exposure MOE**	100	NOAEC
Inhalation	87	6	5	30	10	8	5	4.9	10	5%	32.0	3	**213**		N/A

Risks were not identified for workers for lung toxicity via inhalation based on quantitative hazard data for a low molecular weight component of the new chemical (MOE = 213; benchmark MOE = 100).

Dermal: Neurotoxicity based on LMW component; uncertain absorption assumed to be conservatively 100%

Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR

	Animal or Human			Human							Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/day Potential Dose Rate (PDR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Body Weight kg	Exposure mg/kg-day	Structural Alert as % of PMN	Margin of Exposure MOE	100	NOAEL
Dermal	20	5	100%	1600	5	100%	80	20	5%	**20.0**	[redacted]	

Risks were identified for workers for systemic toxicity via dermal contact based on quantitative hazard data for a low molecular weight component of the new chemical (MOE = 20; benchmark MOE = 100).

[redacted]

3.2.2 General Population Calculations

Population Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR											
	Animal or Human			Human						Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/kg-day Acute Dose Rate (ADR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Multiplier for Susceptible Subpopulations	Structural Alert as % of PMN	Margin of Exposure MOE	100	NOAEL
Drinking Water	20	5	100%	4.24E-02	7	100%	1.0	5%	**6,739**	[redacted]	
Drinking Water	20	5	100%	4.24E-02	7	100%	4.2	5%	**1,604**		

Risks were not identified for the general population for systemic effects via drinking water exposure based on quantitative hazard data for a low molecular weight component of the new chemical (MOE_{adult}= 6,739; MOE_{infant}=1,604; benchmark MOE = 100).

3.2.3 Consumer Calculations

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.